

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

AA539M



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification⁴ : A61K 7/00, 7/09, 7/15 A61K 7/155	A1	(11) International Publication Number: WO 86/ 05389 (43) International Publication Date: 25 September 1986 (25.09.86)
(21) International Application Number: PCT/US86/00488 (22) International Filing Date: 10 March 1986 (10.03.86) (31) Priority Application Numbers: 713,293 797,687 (32) Priority Dates: 18 March 1985 (18.03.85) 13 November 1985 (13.11.85) (33) Priority Country: US (71) Applicant: PRODUCT RESOURCES INTERNATIONAL, INC. [US/US]; 1414 Avenue of the Americas, New York, NY 10019 (US). (72) Inventor: MACKLES, Leonard ; 311 East 23rd Street, New York, NY 10023 (US). (74) Agent: AMSTER, Morton; Amster, Rothstein & Ebenstein, 90 Park Avenue, New York, NY 10016 (US).		(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: EXOTHERMIC STABLE FOAM COMPOSITIONS (57) Abstract A stable, anhydrous aerosol foam capable of suspending up to 50% by weight of dispersed anhydrous particulate solids capable of absorbing water exothermically is prepared from such solids and a foamable liquid oil, a foaming agent and a propellant.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GA	Gabon	MR	Mauritania
AU	Australia	GB	United Kingdom	MW	Malawi
BB	Barbados	HU	Hungary	NL	Netherlands
BE	Belgium	IT	Italy	NO	Norway
BG	Bulgaria	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali		
FR	France				

EXOTHERMIC STABLE FOAM COMPOSITIONS
Description of the Invention

This application is a continuation-in-part of Patent Application Serial No. 713,293, filed March 18, 1985.

The use of anhydrous particulate absorbant materials capable of sorbing water exothermically in autoheating cosmetic and similar compositions is well known. Menkart, et al., in Canadian Patent No. 748,049, disclose liquids, creams, gels and pastes which utilize materials such as silica gel, activated alumina, and alkali metal alumino silicate molecular sieves (Zeolites) in non-aqueous vehicles which warm automatically on contact with moisture in or on the skin. Analgesic preparations containing Zeolite in an anhydrous liquid are disclosed in U.S. Patent No. 4,379,143. Cosmetic vehicles comprising a carboxy vinyl polymer and Zeolites are disclosed in U.S. Patent No. 4,362,715. A toothpaste containing Zeolite is disclosed in U.S. Patent No. 4,349,533.

Despite the foregoing disclosures, no products based on such formulations have been successfully marketed because such formulations are cosmetically inelegant, i.e., they are very oily, greasy and pasty in consistency; spread poorly on the skin, and leave the skin with a greasy feel and appearance. These undesirable characteristics result from the fact that water or hydroxylated solvents such as alcohols or glycols must

normally be omitted in order to preserve the exothermic reactivity of the particulate absorbants.

Copending U.S. Patent Application Serial No. 778,026 filed on September 20, 1985 describes and claims
5 novel anhydrous aerosol foams which are capable of suspending up to 50% by weight of a dispersed solid without causing malfunction of an aerosol valve. The novel properties of these aerosol foams make them suitable for use as delivery systems for a wide range of
10 therapeutic agents and provide an alternative to tablets or capsules, which are difficult to swallow or bad tasting liquid medications.

It has now been unexpectedly discovered that the aerosol foam delivery system described and claimed in
15 copending Application Serial No. 778,026 is capable of functioning to provide a cosmetically elegant delivery system for formulations containing particulate absorbant materials capable of sorbing water exothermically alone or in combination with other therapeutic or cosmetic
20 ingredients. Specifically, it has now been found that a stable, anhydrous aerosol foam or whip capable of suspending up to 50% by weight of a dispersed solid can be prepared from a foamable anhydrous liquid oil; a foaming agent; and controlled amounts of a propellant which are
25 sufficient to produce a stable foam rather than a spray. The foam, as delivered from an aerosol canister, has the consistency of whipped cream, is stable for extended

3

periods and is hostile to the growth of micro-organisms.

While not wishing to be limited to any particular theory, it is presently believed that the expansion of the formulations caused by the presence of a propellant causes the product to spread in the form of a thin film on the skin, thereby giving a soft, silky, and cosmetically elegant feel. The observed effect is analogous to a comparison between whipped cream and butter. While both of these products are produced from cream, butter is a dense, greasy water in oil emulsion, whereas whipped cream is a light air in oil emulsion in which the oil is extended over a much greater volume, thereby masking its greasy properties to a substantial extent. In the present invention, by foaming the oils with a propellant to produce a low density aerated whip or mousse, the greasy property of the oil in the formulation is eliminated. The invention makes it possible to achieve the foregoing results without valve clogging due to a novel combination of ingredients that produces a high viscosity formulation capable of keeping the small solids particles dispersed and of lubricating the aerosol valve.

The foamable, anhydrous liquid oils utilized in the present invention are varied and of no great critical significance. Typical among the organic oils useful for the present invention are those such as soybean oil, partially hydrogenated soybean oil, linseed oil, corn oil, peanut oil, sunflower oil, cottonseed oil, olive oil,

castor oil, liquid petrolatum, oleic acid, lauric acid, and mono- and diglyceride oils. As indicated above, the basic criterion for a liquid oil utilizable in the present invention is that it is foamable.

5 Typically, the oils utilized in the present invention are present in the formulation in a percentage of 40 to 95% by weight of the total composition. A preferred range is 50 to 70% by weight of the total composition. The amount of oil may be varied based upon
10 the nature and amount of the other ingredients in the formulation, such as the amount of dispersed solids. Ordinarily, the percentage amount of each other ingredient in the formulation is first selected and the oil is the ingredient added to bring the formulation to 100%.

15 Foaming agents utilizable in the present invention are selected from the group consisting of lecithin, various polyol fatty acid esters and mixtures thereof, or solid silicone copolymers as disclosed in U.S. Patent No. 3,770,648. Lecithin is the commercial name for
20 a class of naturally occurring compounds derived from soybeans. These compounds are phosphatides and phospholipids. The principal components of lecithin are a naturally occurring mixture of phosphatidyl choline, phosphatidyl ethanolamine, inositol phosphatides and
25 related phosphorous containing lipids. Chemically, lecithin is described as phosphatidyl choline and is a mixture of the diglycerides of stearic, palmitic and oleic

acids linked to the choline ester of phosphoric acid. It is available commercially as a 60% solution in soybean oil or as a granular powder essentially free of soybean oil. A hydroxylated lecithin, modified to increase the hydrophilic properties is also commercially available. This hydroxylated lecithin is commonly supplied as a 60% solution in soybean oil.

The polyol fatty acid esters utilizable in the present invention are commercial products and are comprised of three types:

1. Glycerol esters of fatty acids.
2. Polyglycerol esters of fatty acids.
3. Sorbitan esters of fatty acids.

The glycerol esters which have been found to be advantageous in generating a suitable anhydrous aerosol foam are prepared by standard esterification methods and have a HLB of between 2.5 and 4.5. Among the preferable glycerol fatty esters utilizable in the present invention are those such as glycerol monostearate (HLB 3.2) and glycerol monooleate (HLB 3.4).

The polyglycerol esters utilizable in the present invention are commercial products prepared by first polymerizing glycerine under alkaline conditions. The polymerization is controlled to yield the particular desired average molecular weight. Investigations indicate that the polymerization of glycerol progresses predominately in a straight-chain manner. The esters are

prepared by reacting the polyglycerols with a specific fatty acid or by the alcoholysis of a triglyceride. By this method, it is possible to prepare esters ranging anywhere from hydrophilic monoesters such as decaglycerol monolaurate to a lipophilic decaglycerol decaoleate.

The polyglycerol esters preferably used in the present invention have an HLB value of between 4.0 and 13.0. These have been found to be most advantageous in generating a suitable anhydrous aerosol foam. Among the preferable polyglycerol esters utilizable in the present invention are those such as: hexaglycerol distearate (HLB 4.0), decaglycerol tetraoleate (HLB 6.0), triglycerol monostearate (HLB 7.0), triglycerol monooleate (HLB 7.0), octaglycerol monostearate (HLB 12.0) and octaglycerol monooleate (HLB 13.0).

The sorbitan fatty acid esters which have been found to be advantageous in generating a suitable anhydrous aerosol foam are commercial products prepared by standard esterification methods and have an HLB of between 3.0 and 7.0. Among the preferable sorbitan esters utilizable in the present invention are those such as sorbitan monostearate (HLB 4.7), sorbitan monooleate (HLB 4.3), and sorbitan mono palmitate (HLB 6.7).

Additionally, a combination of any of the polyol fatty acid esters may be utilized in the present invention.

The polyol fatty acid esters are somewhat more hydrophilic than lecithin so that their use allows the

foamable, anhydrous liquid oil to be more easily dispersed when contacted with an aqueous medium. Additionally, they may be used in conjunction with lecithin in the same system which causes the lecithin to become more hydrophilic and therefore more water miscible than the lecithin alone.

The solid silicone copolymers which are useful as foaming agents in this invention are fully disclosed in U.S. Patent No. 3,770,648 and that disclosure is hereby incorporated by reference.

The foaming agent utilized in the present invention is present in an amount of from 2 to 40% by weight. The amount of foaming agent utilized depends upon the particular foaming agent being utilized, the particular foamable, anhydrous liquid oil being utilized and the propellant system. A preferred range of foaming agent is from about 3 to 15% by weight of the composition, with 4 to 6% being especially preferred. It is a particularly desirable additional feature of the foaming agents that they possess surfactant properties and, therefore, affect the rate at which the insoluble solid active ingredient of the foam is released. Accordingly, some variations in the amount of foaming agent in a particular formulation may be purposely chosen based on the nature of the solid active ingredient in order to control the rate of release.

The propellant can be selected from the class of

hydrocarbons that are gaseous under atmospheric pressures and liquefy when compressed, or certain fluorocarbons such as FREON 115; monochloropentafluorethane; FREON 12; dichlorodifluoromethane; Dymel 22; chlorodifluoromethane; Dymel 152; 1, 1, difluoroethane; and dimethylether. Propellants other than the liquefied hydrocarbon or fluorocarbon gases can be used including compressed gases like nitrogen, nitrous oxide and carbon dioxide, but they do not produce the most desirable foams over the life of the product in use. The most commonly used propellants are propane, butane and isobutane. Since these liquefied gases are soluble in the oil vehicle of the composition, there is a resulting reduction in their vapor pressure. Therefore, it is most advantageous to use propane since it has the highest pressure of the three hydrocarbon propellants and, even when dissolved in the low concentrations normally employed in this invention, produces a product with a pressure of 30-40 pounds per square inch over atmospheric pressure. This pressure is required to eject the foam from the container and produce a stable, dense foam. However, since propane is soluble in the oil base, there is very little pressure drop from the first to the last actuation of the aerosol valve and a satisfactory foam is produced when each dose is expelled.

The amount of propellant used is critical since too much will produce an undesirable spray rather than the desired stable, measurable foam. Amounts of propellant in

the range of from 1-10 wt. % are operative, but 4-6 wt. % is the preferred concentration based upon the total weight of the contents of the aerosol container. The amount of propellant used may vary somewhat, depending upon the nature and amount of the other ingredients in the composition but, in all cases, the lowest amount sufficient to form a stable, measurable foam without forming an unmeasurable spray will be selected.

The anhydrous solid particulate matter capable of sorbing water exothermally which can constitute between 10 and 50% by weight of the basic composition, includes any materials in this class which are physiologically compatible with hair and skin and which are further compatible with any pharmaceutically active agents to be added to said basic composition. In this general category may be included calcium chloride, silica gel, activated alumina and alkali metal alumino silicate molecular sieves. The latter generally being known as Zeolites. Of particular interest, are the Zeolites, especially those of the general formula $M_x/n[AL_2)_x(SiO_2)_y]$, wherein X and Y are integers greater than 6, the molecular ratio of X to Y is 0.1 to 1.1 and M is a metal with a valence of n. These Zeolites are preferably in the activated foam which effectively means that they have been pretreated in such a manner that they contain not in excess of 5% by weight of water.

The anhydrous aerosol foam of the present

invention may be used as a vehicle for any of a large variety of active pharmaceutical materials or cosmetic ingredients in addition to the exothermic material.

The foam itself may be used as a carrier for a large variety of additional hair or skin modifying agents. Such modifying agents may be cosmetics or pharmaceuticals and may include both prescription and non-prescription agents. Thus, there may be incorporated hair dyes and hair conditioning agents, shampoos, shaving
5 soaps, skin emollients, anti-dandruff agents, anti-seborrheic agents, anti-inflammatory agents, muscle relaxants, and any other generally accepted agents for modifying the condition of hair, the surface of the skin and subdermal areas generally treated by topical
10 application of physiologically active materials. As examples of conditioning agents, there may be mentioned the quaternary salts of fatty acids having a carbon content of 12 to 18 carbon atoms, generally accepted conditioning oils such as isopropyl myristate, isopropyl
15 palmitate, isopropyl sebacate and the like may be used; as anti-dandruff agents, there may be utilized zinc pyrithione or selenium sulfide; as anti-seborrheic or anti-inflammatory agents there may be mentioned hydrocortisone; as hair dyes any of the conventionally
20 used hair dyes may be employed. This list is to be considered as merely illustrative and in no way limiting. Additional agents not listed herein would be apparent to

11

those skilled in the art.

The amount of these added agents will depend upon the required effective concentration and whether they are solid or liquid. If they are liquid, they may
5 constitute up to 95% of the total composition by weight, although 20 to 65% is to be preferred. If they are solids, they may constitute up to 40% of the total composition, provided that the combined proportion of the anhydrous solid particulate material and said solid agent
10 does not exceed 50% of the entire composition.

A particularly important and surprising feature of the foams of this invention is their ability to suspend high concentrations, i.e., up to 50% by weight, of solids. Preferably, the suspended particles are ground to
15 a very fine particle size since this facilitates the formation and maintenance of a uniform dispersion and prevents clogging. Particle sizes less than 100 microns, preferably in the range of 50 to 100 microns in diameter, are employed.

20 The foam of the present invention can contain up to 50 wt. % of suspended solid particles without any appreciable valve malfunctioning, and will usually contain in excess of 15 wt. % of such solid particles since a primary purpose of the foam system is to deliver a high
25 concentration of the active ingredient in the solid particles in a relatively small dose. This ability to suspend high percentages of solids without valve

12

malfunctioning enables the aerosol foam system of the present invention to be utilized for a wide variety of formulations. The reasons for the unique ability of the foams to suspend such a high concentration of solids without valve clogging are not fully understood, but it is believed to result from a combination of the small particle size, the high viscosity of the foam formulation due to its low propellant content which aids in keeping the particles dispersed and reduces agglomeration and settling, and the lubricating effect of the oil on the valve.

The foams of the present invention are prepared by conventional formulating techniques. Thus, typically, the foamable anhydrous liquid oil and the foaming agent are mixed together along with any other soluble ingredients of the composition. The solid to be dispersed is then added and the resultant mixture passed through an appropriate mill to ensure uniform particle size. The batch is then submitted for aerosol filling to an aerosol can. An aerosol valve is placed on the can and the can is crimped. The propellant is then added by pressure filling.

In addition to the active solid to be dispersed in the foam and the essential ingredients of the foam, there may also be incorporated in the foams of the present invention any of a variety of additives or a combination thereof, commonly added to aerosol compositions or to toiletries, cosmetics, or pharmaceuticals. Typically,

13

such additives are those such as emollients, lubricants, humectants, abrasives, perfumes and colorants.

It will be apparent to those skilled in the art that many modifications, both of materials and methods, may be practiced without departing from the purpose and intent of the disclosure.

EXAMPLE 1

Hot Oil Hair Mousse Foam

	1. Valfor 950, anhydrous sod.	
10	aluminosilicate (P.Q. Corp.)	35.00%
	2. Cabosil M-5, Fumed Silica	.50
	3. Decaglycerol Tetra Oleate	6.00
	4. Polyethylene glycol 400 dioleate	2.00
	5. Soybean Oil, partially	
15	hydrogenated	51.20
	6. Propane	5.00
	7. Fragrance	<u>0.30</u>
		100.00%

Procedure:

The items #3, 4, 5 and 7 are mixed at ambient temperature until uniform. The powders #1 and #2 are added and mixed until uniform. The batch is passed through a colloid mill and then submitted for aerosol filling during which the propane is added.

Use

When used as a hot oil hair mousse foam, it is

14

preferred, but not essential, that the hair be washed and touch dried with a towel so as to leave the hair moist but not dripping. A sufficient amount of mousse is applied to the hair to cover the entire area and worked into the hair. The contact with moist hair will cause the mousse to heat up giving rise to the desired heat conditioning. The composition can be left on the hair as long as desired. In one modification of its use, a towel may be wrapped around the head in order to preserve the heat factor for somewhat longer.

While it is not totally necessary to do so, it is generally preferred to wash the composition out of the hair with a mild shampoo in the conventional manner.

The essential ingredients are:

1. The heat generating solid (Valfor 950) which is exothermic upon contact with water on the hair and scalp. Other heat generating anhydrous solids can be used in place of the Valfor 950 in the same preparation, e.g., anhydrous calcium chloride, dried magnesium sulfate.
 2. The foaming agent can be replaced by lecithin or the sorbitan mono esters or mixtures thereof or silicone #1252.
 3. The foamable oil is any liquid anhydrous oily material.
- The propellant is propane or any high pressure aerosol propellant.

15

EXAMPLE 2Hot Oil Anti-dandruff Mousse Foam

	1.	Valfor 950, anhydrous sod.	
		aluminosilicate (P.Q. Corp)	35.00%
5	2.	Cabosil M-5, Fumed Silica	.50
	3.	Sorbitan Mono Stearate	4.00
	4.	Polyethylene glycol 400 dioleate	2.00
	5.	Soybean Oil, partially	
		hydrogenated	51.20
10	6.	Propane	5.00
	7.	Zinc Pyrithione	2.00
	8.	Fragrance	<u>0.30</u>
			100.00%

Procedure:

The items #3, 4, 5, 7 and 8 are mixed at 60°C.
15 temperature until uniform. The powders #1 and #2 are
added and mixed until uniform. The batch is cooled and
passed through a colloid mill and then submitted for
aerosol filling during which the propane is added.

Use

20 It is preferred, but not essential, that the
hair be washed and touch dried with a towel so as to leave
the hair moist but not dripping. A sufficient amount of
mousse is applied to the hair to cover the entire area and
worked into the hair. The contact with moist hair will
25 cause the mousse to heat up giving rise to the desired

16

heat conditioning. The composition can be left on the hair as long as desired. In one modification of its use, a towel may be wrapped around the head in order to preserve the heat factor for somewhat longer.

- 5 While it is not totally necessary to do so, it is generally preferred to wash the composition out of the hair with a mild shampoo in the conventional manner

EXAMPLE 3

Hot Oil Hair Conditioning Mousse Foam

10	1.	Valfor 950, anhydrous sod.	
		aluminosilicate (P.Q. Corp)	35.00%
	2.	Cabosil M-5, Fumed Silica	.50
	3.	Lecithin, Powdered	3.00
	4.	Glycerol Mono Stereate	4.00
15	5.	Polyethylene glycol 400 dioleate	2.00
	6.	Cotton Seed Oil	46.20
	7.	Propane	5.00
	8.	Stearyl dimethyl benzyl	
		ammonium chloride	4.00
20	9.	Fragrance	<u>0.30</u>
			100.00%

Procedure:

The items #3, 4, 5, 6 and 8 are mixed at 60° C. temperature until uniform. The powders #1 and #2 are added and mixed until uniform. The batch is cooled and
 25 passed through a colloid mill and then submitted for

17

aerosol filling during which the propane is added.

Use

It is preferred, but not essential, that the hair be washed and touch dried with a towel so as to leave
5 the hair moist but not dripping. A sufficient amount of mousse is applied to the hair to cover the entire area and worked into the hair. The contact with moist hair will cause the mousse to heat up giving rise to the desired heat conditioning. The composition can be left on the
10 hair as long as desired. In one modification of its use, a towel may be wrapped around the head in order to preserve the heat factor for somewhat longer.

While it is not totally necessary to do so, it is generally preferred to wash the composition out of the
15 hair with a mild shampoo in the conventional manner.

EXAMPLE 4

Hot Oil Anti-Seborrheic Emollient Mousse Foam

	1.	Valfor 950, anhydrous sod.	
		aluminosilicate (P.Q. Corp)	35.00%
20	2.	Cabosil M-5, Fumed Silica	.50
	3.	Dow Corning Silicone #1252	
		(50% silicone copolymer,	
		50% isobutyl isobutyrate)	4.00
	4.	Polyethylene glycol 400 dioleate	2.00
25	5.	Sunflower Oil	50.00
	6.	Propane	5.00

18

7.	Hydrocortisone Acetate	3.00
8.	Fragrance	<u>0.30</u>
		100.00%

Procedure:

5 The items #3, 4, 5, 7 and 8 are mixed at ambient temperature until uniform. The powders #1 and #2 are added and mixed until uniform. The batch is passed through a colloid mill and then submitted for aerosol filling during which the propane is added.

Use

10 The composition may be used as a skin emollient. In this use the affected area is washed, the surplus water shaken off, and the mousse applied to the affected area.

15 This mousse may be used as an anti-seborrheic hair mousse foam. It is preferred, but not essential, that the hair be washed and touch dried with a towel so as to leave the hair moist but not dripping. A sufficient amount of mousse is applied to the hair to cover the entire area and worked into the hair. The contact with
20 moist hair will cause the mousse to heat up giving rise to the desired heat conditioning. The composition can be left on the hair as long as desired. In one modification of its use, a towel may be wrapped around the head in order to preserve the heat factor for somewhat longer.

19

EXAMPLE 5Hot Oil Hair Dye Mousse Foam

	1.	Valfor 950, anhydrous sod.	
		aluminosilicate (P.Q. Corp)	35.00%
5	2.	Cabosil M-5, Fumed Silica	.50
	3.	Dow Corning Silicone #1252	
		(50% silicone copolymer,	
		50% isobutyl isobutyrate)	4.00
	4.	Polyethylene glycol 400 dioleate	2.00
10	5.	Peanut Oil	50.06
	6.	Propane	5.00
	7.	Maxilon Blue GRL(500%)	0.3
		Deorlene Orange 7GL	1.2
		Deorlene Orange 2GL	0.3
15		Basacryl Red FB	1.0
	8.	Fragrance	<u>0.30</u>
			100.00%

Procedure:

The items #3, 4, 5, 7 and 8 are mixed at ambient temperature until uniform. The powders #1 and #2 are added and mixed until uniform. The batch is passed through a colloid mill and then submitted for aerosol filling during which the propane is added.

Use

When used as a hair dye, it is preferred, but not essential, that the hair be washed and touch dried

20

with a towel so as to leave the hair moist but not dripping. A sufficient amount of mousse is applied to the hair to cover the entire area and worked into the hair. The contact with moist hair will cause the mousse to heat up giving rise to the desired heat conditioning. The composition can be left on the hair as long as desired. In one modification of its use, a towel may be wrapped around the head in order to preserve the heat factor for somewhat longer.

While it is not totally necessary to do so, it is generally preferred to wash the composition out of the hair with a mild shampoo in the conventional manner.

EXAMPLE 6Warm Topical Analgesic Mousse

15	1. Menthol	10.0%
	2. Sodium Alumino Silicate	
	(Valfor 950)	35.0
	3. Cabosil M-5	1.0
	4. Sorbitan Monostearate	4.0
20	5. Decaglycerol Tetraoleate	6.0
	6. Soybean Oil	10.0
	7. Isopropyl Myristate	30.0
	8. Propane	<u>4.0</u>
		100.0%

Procedure:

Items 4, 5, 6 and 7 are mixed at 60°C.

21

temperature until uniform. Items 2 and 3 are added and mixed until uniform. The mixture is cooled to 40°C. and item 1 is added and mixed until uniform. The mixture is then submitted for aerosol filling during which the propane is added.

EXAMPLE 7Warm Topical Analgesic Mousse

	1. Menthyl Salicylate	15.0%
	2. Sodium Alumino Silicate	
10	(Valfor 950)	35.0
	3. Cabosil M-5	1.0
	4. Sorbitan Monostearate	4.0
	5. Decaglycerol Tetraoleate	6.0
	6. Soybean Oil	34.0
15	7. Propane	<u>5.0</u>
		100.0%

Procedure:

Items 4, 5, and 6 are mixed at 60°C. temperature until uniform. Items 2 and 3 are added and mixed until uniform. The mixture is cooled to 40°C. and item 1 is added and mixed until uniform. The mixture is then submitted for aerosol filling during which the propane is added.

WHAT IS CLAIMED IS:

1. An anhydrous aerosol foam composition comprising a foamable liquid oil, a foaming agent and a propellant, said propellant being present in an amount
5 sufficient to produce a stable, measurable foam but insufficient to produce a spray when said composition is ejected through an aerosol valve, and dispersed solid particles, said particles comprising substantially anhydrous particulate material capable of absorbing water
10 exothermically.
2. The composition of claim 1 wherein said propellant comprises 1 to 10 wt. % of said composition.
3. The composition of claim 2 wherein said particles comprise 10 to 50 wt. % of said composition.
- 15 4. The composition of claim 3 wherein the average size of said solid particles is in the range of 50 to 100 microns.
5. A composition of claim 1 containing 10 to 50% of activated Zeolite of the formula
20
$$M_x/n [(AlO_2)_x(SiO_2)_y]$$
 wherein x and y are integers greater than 6, the molar ratio of x to y is 0.1 to 1.1 and M is a metal with the valence of n.
6. The composition of claim 1 wherein said
25 propellant comprises 1 to 10 wt. % of said composition, said foaming agent comprises 2 to 40 wt. % of said composition, said solid particles comprise 10 to 50 wt. %

of said composition and the balance of said composition is said liquid oil.

7. The composition of claim 6 wherein said propellant is a hydrocarbon.

5 8. The composition of claim 6 wherein said propellant is a fluorocarbon.

9. The composition of claim 6 wherein said liquid oil is selected from the group consisting of soybean oil, partially hydrogenated soybean oil, linseed
10 oil, corn oil, peanut oil, sunflower oil, cottonseed oil, olive oil, castor oil, liquid petrolatums, oleic acids, lauric acid and mono- and diglyceride oils.

10. The composition of claim 6 wherein the foaming agent is selected from the group consisting of
15 solid silicone polymers, lecithin, polyglycerol esters of fatty acids having an HLB value of between 4.0 and 13.0, glycerol esters of fatty acids having an HLB value of between 2.5 and 4.5, sorbitan esters of fatty acids having an HLB value of between 3.0 and 7.0 and mixtures thereof.

20 11. The composition of claim 10 wherein said foaming agent comprises 2 to 40 wt. % of said composition.

12. The composition of claim 10 wherein the foaming agent is a mixture of lecithin and glycerol monostearate.

25 13. The composition of claim 10 wherein the foaming agent is a mixture of lecithin and decaglycerol tetraoleate.

14. The composition of claim 10 wherein the foaming agent is triglycerol monooleate.

15. The composition of claim 10 wherein the foaming agent is decaglycerol tetraoleate.

5 16. The composition of claim 10 wherein the foaming agent is sorbitan monostearate.

17. The composition of claim 10 wherein the foaming agent is a mixture of decaglycerol tetraoleate and sorbitan monostearate.

10 18. The composition of claim 10 wherein the foaming agent is a mixture of decaglycerol tetraoleate and glycerol monostearate.

19. The composition of claim 10 wherein the foaming agent is a mixture of decaglycerol tetraoleate, sorbitan monostearate and glycerol monostearate.

15 20. The composition of claim 10 wherein the foaming agent is a mixture of sorbitan monostearate and glycerol monostearate.

21. The composition of claim 10 wherein the foaming agent is from about 3 to 15 wt. % of the composition.

22. The composition of claim 10 wherein the foaming agent is a mixture of lecithin, sorbitan monostearate and glycerol monostearate.

25 23. The composition of claim 10 wherein the foaming agent is a mixture of lecithin, sorbitan monostearate and decaglycerol tetraoleate.

25

24. The composition of claim 10 wherein the foaming agent is a mixture of lecithin and sorbitan monostearate.

25. As an article of manufacture, a pressurized aerosol container, said container having therein an anhydrous aerosol foam composition comprising a foamable liquid oil, a foaming agent and a propellant, said propellant being present in an amount sufficient to produce a stable, measurable foam but insufficient to produce a spray when said composition is ejected through an aerosol valve, and dispersed solid particles, said particles comprising substantially anhydrous particulate material capable of absorbing water exothermically.

26. The composition of claim 25 wherein said propellant comprises 1 to 10 wt. % of said composition, said foaming agent comprises 2 to 40 wt. % of said composition, said solid particles comprise at least 10 wt. % of said composition and the balance of said composition is said liquid oil.

27. The composition of claim 25 wherein said propellant is a hydrocarbon.

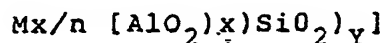
28. The composition of claim 25 wherein said propellant is propane.

29. The composition of claim 25 wherein said liquid oil is selected from the group consisting of soybean oil, partially hydrogenated soybean oil, linseed oil, corn oil, peanut oil, sunflower oil, cottonseed oil,

olive oil, castor oil, liquid petrolatums, oleic acids, lauric acid and mono- and diglyceride oils.

30. The composition of claim 25 wherein the foaming agent is selected from the group consisting of
5 solid silicone polymers, lecithin, polyglycerol esters of fatty acids having an HLB value of between 4.0 and 13.0, glycerol esters of fatty acids having an HLB value of between 2.5 and 4.5. sorbitan esters of fatty acids having an HLB value of between 3.0 and 7.0 and mixtures thereof.

10 31. A composition of claim 25 containing 10 to 50% of activated Zeolite of the formula



wherein x and y are integers greater than 6, the molar ratio of x to y is 0.1 to 1.1 and M is a metal with the
15 valence of n.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US. 86/00488

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC ⁴ : A 61 K 7/00; A 61 K 7/09; A 61 K 7/15; A 61 K 7/155																	
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched ⁷</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 25%; border-bottom: 1px solid black;">Classification System</th> <th style="border-bottom: 1px solid black;">Classification Symbols</th> </tr> <tr> <td style="border-right: 1px solid black; padding: 5px;">IPC⁴</td> <td style="padding: 5px;">A 61 K 7/00; A 61 K 9/00</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸</div>			Classification System	Classification Symbols	IPC ⁴	A 61 K 7/00; A 61 K 9/00											
Classification System	Classification Symbols																
IPC ⁴	A 61 K 7/00; A 61 K 9/00																
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 10%; border-bottom: 1px solid black;">Category ⁹</th> <th style="width: 70%; border-bottom: 1px solid black;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 20%; border-bottom: 1px solid black;">Relevant to Claim No. ¹³</th> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">US, A, 3250680 (J. MENKART et al.) 10 May 1966 see column 1, lines 32-54; column 2, lines 12-35; claims</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1,2,4-31</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">US, A, 4379143 (H.D. SHERRY) 5 April 1983 see column 1, lines 10-14; column 2, lines 30-35; column 3, lines 9-16; claims (cited in the application)</td> <td style="text-align: center; vertical-align: top; padding: 5px;">4,5,9-20,29,31</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">US, A, 3770648 (L. MACKLES) 6 November 1973 see column 4, lines 17-46; column 4, lines 52-71; column 5, lines 11-22; claims 1,2 (cited in the application)</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1,2,6-30</td> </tr> <tr> <td colspan="3" style="text-align: center; padding: 10px;">-----</td> </tr> </table>			Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	Y	US, A, 3250680 (J. MENKART et al.) 10 May 1966 see column 1, lines 32-54; column 2, lines 12-35; claims	1,2,4-31	Y	US, A, 4379143 (H.D. SHERRY) 5 April 1983 see column 1, lines 10-14; column 2, lines 30-35; column 3, lines 9-16; claims (cited in the application)	4,5,9-20,29,31	Y	US, A, 3770648 (L. MACKLES) 6 November 1973 see column 4, lines 17-46; column 4, lines 52-71; column 5, lines 11-22; claims 1,2 (cited in the application)	1,2,6-30	-----		
Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³															
Y	US, A, 3250680 (J. MENKART et al.) 10 May 1966 see column 1, lines 32-54; column 2, lines 12-35; claims	1,2,4-31															
Y	US, A, 4379143 (H.D. SHERRY) 5 April 1983 see column 1, lines 10-14; column 2, lines 30-35; column 3, lines 9-16; claims (cited in the application)	4,5,9-20,29,31															
Y	US, A, 3770648 (L. MACKLES) 6 November 1973 see column 4, lines 17-46; column 4, lines 52-71; column 5, lines 11-22; claims 1,2 (cited in the application)	1,2,6-30															

<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 48%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p> </div> </div>																	
IV. CERTIFICATION <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; padding: 5px;">Date of the Actual Completion of the International Search 16th June 1986</td> <td style="width: 50%; border-bottom: 1px solid black; padding: 5px;">Date of Mailing of this International Search Report 16 JUL 1986</td> </tr> <tr> <td style="border-bottom: 1px solid black; padding: 5px;">International Searching Authority EUROPEAN PATENT OFFICE</td> <td style="border-bottom: 1px solid black; padding: 5px;">Signature of Authorized Officer M. VAN MOL </td> </tr> </table>			Date of the Actual Completion of the International Search 16th June 1986	Date of Mailing of this International Search Report 16 JUL 1986	International Searching Authority EUROPEAN PATENT OFFICE	Signature of Authorized Officer M. VAN MOL											
Date of the Actual Completion of the International Search 16th June 1986	Date of Mailing of this International Search Report 16 JUL 1986																
International Searching Authority EUROPEAN PATENT OFFICE	Signature of Authorized Officer M. VAN MOL																

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO.

PCT/US 86/00488 (SA 12537)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 02/07/86

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 3250680		None	
US-A- 4379143	05/04/83	CA-A- 1171781	31/07/84
US-A- 3770648	06/11/73	DE-A, C 2234316	25/01/73
		FR-A, B 2157784	08/06/73
		GB-A- 1376649	11/12/74
		AU-A- 4236972	22/11/73
		CA-A- 984257	24/02/76
		SE-B- 393395	09/05/77

For more details about this annex :
see Official Journal of the European Patent Office, No. 12/82